4100 E. Milham Avenue
Kalamazoo, MI 49001
t: 269 323 7700 f: 269 324 5412
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JUL 17 2008

stryker
Instruments

K080450

510(k) Summary

Device Sponsor:
Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, MI 49001
(p) 269-323-7700
(f) 269-324-5412

Registration No.:
1811755

Trade Name:
Stryker® Power Tool Navigator

Common Name:
Power Tool Navigator

Classification Name:
Stereotaxic Instruments

Equivalent to:
K993239 Stryker® Navigation System – Neuro Module
K010204 Stryker® Navigation System – KneeTrack Module
K022365 Stryker® Navigation System – Hip Module

Device Description:
The Stryker® Power Tool Navigator (PTN) attachment is a tracking device designed for use with Stryker Surgical Power Tools. The PTN attachment is an optical surgical navigation tracker that attaches to a power tool, allowing that tool to be tracked by a Stryker Navigation System. The device employs an array of optical IR LEDs and an IR communications link to interface with the Navigation System.

Indications for Use:
Stryker® Power Tool Navigator attachment is intended to enable spatial localization and identification of Stryker Power Tools by the Stryker® Navigation System

Substantial Equivalence (SE) Rational:
Stryker® Power Tool Navigator attachment is equivalent in intended use, safety, and effectiveness to existing devices being marketed by Stryker.

Safety and Effectiveness:
The **Stryker® Power Tool Navigator** attachment does not raise any new safety and efficacy concerns when compared to a similar device already legally marketed. The **Stryker® Power Tool Navigator** attachment is, therefore, substantially equivalent to the existing device. **Stryker® Power Tool Navigator attachment** is designed and manufactured in accordance with Stryker Instrument's Quality Management System covered by QSR 21CFR 820.

Submitted by:
Becky Ditty
Senior Regulatory Affairs Representative

Signature

Date Submitted:
2/15/8

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2008

Stryker Corporation
% Ms. Becky Ditty
Regulatory Analyst
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

Re: K080450
Trade/Device Name: Stryker® Power Tool Navigation
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: June 16, 2008
Received: June 19, 2008

Dear Ms. Ditty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K080450

Device Name: Stryker® Power Tool Navigator

Indications for Use

The Stryker® Power Tool Navigator attachment is intended to enable spatial localization and identification of Stryker Power Tools by the Stryker® Navigation System.

Prescription Use ___X___ and/or Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K080450